

MS APPEAL BRIEF - PATENTS PATENT 0020-4518P

IN THE U.S. PATENT AND TRADEMARK OFFICE

In re application of

Before the Board of Appeals

Noriko MIZOBUCHI et al.

Appeal No.:

Appl. No.: 09/242,700

Group:

1616

Filed:

April 19, 1999

Examiner: Sharmila Gollamudi

Conf.:

1380

For:

A STABLE OINTMENT CONTAINING ASPIRIN

## REPLY BRIEF TRANSMITTAL FORM

MS APPEAL BRIEF - PATENTS Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

August 16, 2004

Sir:

Transmitted herewith is a Reply Brief (in triplicate) on behalf of the appellants in connection with the above-identified application.

П The enclosed document is being transmitted via the Certificate of Mailing provisions of 37 C.F.R. § 1.8.

The Examiner's Answer was mailed on June 14, 2004.

An extension of time under 37 C.F.R. § 1.136(b) to was and was approved on requested on

П Please charge Deposit Account No. 02-2448 in the amount of \$0.00. A triplicate copy of this sheet is attached.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

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Attachment(s)

MSW/GMD/jmb

0020-4518P

(Rev. 02/12/2004)



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REPLY BRIEF FOR THE APPELLANT UNDER 37 C.F.R. §1.193(b)

IN THE U.S. PATENT AND TRADEMARK OFFICE

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For:

A STABLE OINTMENT CONTAINING ASPIRIN

## REPLY BRIEF FOR THE APPELLANT UNDER 37 C.F.R. §1.193(b)

Assistant Commissioner for Patents Washington, DC 20231

Sir:

The present reply brief for the Appellants is submitted in response to the Examiner's Answer of June 14, 2004, pursuant to 37 C.F.R. 1.193(b).

Appellants' comments contained in the March 29, 2004 Appeal Brief are herein incorporated by reference in their entirety. Appellants take this opportunity to respond to the Examiner's comments contained in the June 14, 2004 Examiner's Answer, since the Examiner has supplemented her arguments of record with

certain observations which were not previously set forth. Rather than reiterating the entirety of Appellants' position, Appellants now focus on the additional observations made by the Examiner.

This appeal is in connection with the sole remaining rejection, i.e., the rejection of claims 14, 16 and 23-27 under 35 U.S.C. § 112, first paragraph wherein the Examiner alleges that the following phrase in claim 14 is "new matter" to the disclosure:

wherein when the base is hydrocarbon gel or a mixture of hydrocarbon gel and petrolatum, the acetyl salicylic acid is in a range of 20 to 30% by weight per total weight, and wherein when the base is petrolatum, the acetyl salicylic acid is in a range of 25 to 30% by weight per total weight.

In support of this rejection, the Examiner states as follows:

Firstly, the examiner points out to page 3, lines 15-16 of the instant specification, wherein applicant states that aspirin is contained in an ointment in the amount of "0.001 to 30% by weight, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by weight". From this disclosure, it is quite clear applicant's preferable range is 0.01 to 20% or 0.05 to However, after the examiner applied 15% by weight. both anticipatory and obviousness art rejections based on an aspirin concentration of 0.01 to 20% and 0.05-15%, the applicant has attempted to carve around the prior art by reciting the instant weight of 25 to 30%. This range is clearly not supported by the

Moreover, the example of line 5, on specification. page 6 of the instant specification utilizes a maximum weight percentage of 25% aspirin. Example 1 utilizes a weight percent of 0.5, example 2 utilizes a weight percent of 8, example 3 utilizes a weight percent of 5, example 4 utilizes a weight percent of 25, example 5 utilizes a weight percent of 0.5, and example 6 utilizes a weight percent of 1. Thus, demonstrating that 25% is the upper limit of the aspirin concentration and not the argued lower limit of the aspirin seen in the unsupported range of 25 to 30%. (See page 4, second paragraph of the Examiner's Answer: emphasis in original).

## Furthermore, the Examiner states:

The examiner notes that on page 3 of the instant specification that applicant states that the base of hydrocarbon preparation may be qel and/or petrolatum. Further, it is noted that page discloses that the amount of aspirin an ointment is in the amount of "0.001 to 30% by weight, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by However, these two statements are not weight." conjunction with each [other] nor do they appear in the same paragraph of each other on page 3. Nowhere in the specification does the applicant state that the criticality of the concentration of the salicylic acid is in accordance to the base nor does the applicant even vaguely link the concentration of the aspirin with the type of base utilized. actuality, the examples teach away from applicant's recitation of 25-30% aspirin in petrolatum base. examiner points to page 6, lines 5 ... [to 8], the only example that utilizes 25% aspirin wherein the bases is a hydrocarbon gel and not the recited petrolatum base. (See page 5, second paragraph of the Examiner's Answer: emphasis in original).

In the above reproduced Examiner's comments, the Examiner goes to great lengths to make the point that the two ranges of

20-30 weight % and 25-30 weight % constitute new matter, since the overall disclosure "teaches away" from these ranges. The Examiner cites no authority in support of this position. In fact, it appears that the Examiner is utilizing an analysis under 35 U.S.C. 103 for obviousness of a claimed subgenus, which is encompassed by a prior art genus of compounds as set forth in In re Baird, 29 U.S.P.Q.2d 1550 (CAFC 1994).

. . . .

Upon careful consideration of the Examiner's arguments, Appellants respectfully hold fast to the position that there is sufficient <code>implicit</code> support for the range of 25-30 wt.% as recited in claim 14, by combining the range of 0.001-30 wt. % as disclosed on page 3, line 15 with the lower limit of 25 wt. % as would be found from the example given on page 6, lines 5-8 of the present specification. Furthermore, Appellants respectfully hold fast to the position that there is similarly sufficient <code>implicit</code> support for the range of 20-30 wt.% as recited in claim 14, by combining the range of 0.001-30 wt.% with the range of 0.01-20 wt.%, both of which are disclosed on page 3, line 15 of the present specification.

Appellants respectfully submit that the courts have not found a violation of the written description requirement of 35 U.S.C. 112, first paragraph in similar factual situations. For

example, in *In re Blaser*, 194 USPQ 122 (CCPA 1977), the use of a concentration value obtained from one of the examples in the specification as an end point in a claimed range satisfied 35 U.S.C. 112, first paragraph. Also, the use of an upper limit value of one range of temperatures as a lower limit value in another claimed range of temperatures satisfied 35 U.S.C. 112, first paragraph. Specifically, the combination of the range of "up to 80°C" with the range of between "60°C and 200°C" was sufficient to support the recitation of a range of 80°C to 200°C.

Lastly, the Examiner finds fault with the fact that Appellants have associated the two ranges of 20-30 weight % and 25-30 weight % with differing bases.

In response, Appellants respectfully submit that the clause asserted by the Examiner as being new matter is simply a proviso. The use of proviso language has long been a sanctioned tool for carving around prior art, see for example, *In re Johnson*, 194 USPQ 187 (CCPA 1977).

Indeed, based on the holdings in *Blaser*, it is proper to find sufficient implicit written description support for the range of 20-30 wt.% by combining the range of 0.001-30 wt.% with the range of 0.01-20 wt.%, both of which are disclosed on page 3, line 15 of the present specification.

Also, it is proper to find sufficient implicit written description support for the range of 25-30 wt.% by combining the range of 0.001-30 wt.% as disclosed on page 3, line 15 with the lower limit of 25 wt.% from the example given on page 6, lines 5-8 of the present specification.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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